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Regulatory Directive DIR2017-01

Management of Submissions Policy

This document describes the process for managing submissions and introduces reporting requirements under the *User Fees Act*.

(publié aussi en français)

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Table of Contents

1.0 Purpose 1
2.0 Implementation 1
3.0 Scope 2
4.0 Instructions for Submitting an Application 3
5.0 The Management of Submissions Policy Process 4
5.1 Completeness Check (Verification and Screening) 5
5.1.1 Verification 5
5.1.2 Screening 5
5.2 Review Stage 6
5.2.1 Science Evaluation 7
5.2.2 Label Review 8
5.2.3 Decision 8
5.3 Public Consultation 8
5.4 Renegotiation of Review Timelines 8
5.5 Measures 8
5.6 Dispute Resolution 9
Appendix I MOSP Performance Timelines for Pest Control Product Applications 11
Table 1 Category A Submission Performance Timelines in Number of Calendar Days (includes new active ingredients, new MRLs and major new use registration) 11
Table 2 Category B Submission Performance Timelines in Number of Calendar Days (includes new formulations, changes in current formulations, new hosts and/or pests added to existing products, new source of currently registered active ingredient, emergency registrations and changes in rates and methods of application) 12
Table 3 Category C Submission Performance Timelines in Number of Calendar Days (includes changes to technical grade active ingredient, product chemistry, new or changed labels, similar products, administrative changes or re-instatements) 13
Table 4 Category D Submission Performance Timelines in Number of Calendar Days 14
Table 5 Category E Submission Performance Timelines in Number of Calendar Days (for research authorisations and research notification) 14
Table 6 Category F Submission Performance Timelines in Number of Calendar Days (Notifications) 15
Table 7 Category L Submission Performance Timelines in Number of Calendar Days (Data protection submissions) 15
Table 8 Category P Submission Performance Timelines in Number of Calendar Days (Pre-submission Consultations) 15
Appendix II Submission Process Using Category A as an Example 17

1.0 Purpose

Pursuant to subsection 6(1) of the *Pest Control Products Act,* no person shall manufacture, possess, handle, store, transport, import, distribute or use a pest control product that is not registered under the *Pest Control Products Act*, except as otherwise authorized under the Act or unless specifically exempted by the *Pest Control Products Regulations*.

The purpose of this version of the Management of Submissions Policy (MOSP) is to update the previous policy as outlined in Regulatory Directive DIR2013-01, *Revised Management of Submissions Policy*:

- To incorporate new submission categories and timelines resulting from cost recovery consultations,
- To incorporate an additional approach to performance reporting that will be used on submissions received on or after 1 April 2017 that are subject to cost recovery fees. This new approach which was proposed in the *Pesticide Cost Recovery Pre-Proposal Notice* (12 December 2014) and in the *Pesticide Cost Recovery Official Notice of Fee Proposal* (19 March 2015) meets the requirements of the *User Fees Act* (UFA) and was finalized after the cost recovery consultations.
- To incorporate changes to the processing of data protection submissions resulting from stakeholder consultations and the publication of *Memorandum to Registrants, Applicants and their Representatives: Data Protection Submission Review Process* (18 December 2014).
- To incorporate information on the processing of pre-market submissions contained in other Pest Management Regulatory Agency (PMRA) documents, i.e. information on tailgater submissions from Regulatory Directive DIR2003-01: *Organizing and Formatting a Complete Submission for Pest Control Products* and information on submissions going on hold pending the payment of fees from the *Guidance Document on Pest Control Product Cost Recovery Fees*, 1997.
- To incorporate changes affecting the processing of pre-market submissions resulting from the public consultations and publication of the Regulatory Directive DIR2016-04: *Management of the Pesticide Re-evaluation Policy*.
- To remove references to conditional registrations as a result of the publication of the Regulatory Directive DIR2016-03: *Final Decision Regarding Conditional Registrations under the Pest Control Products Regulations*.
- To remove references to Program 914 as a result of discussions at the Economic Management Advisory Committee (EMAC) meetings in 2015.

2.0 Implementation

The following changes affect submissions received on or after 1 April 2017:

2.1 A new 180 day review timeline applies to certain category C submissions (Appendix I, Table 3).

2.2 Category F Notification submissions have been added to the MOSP. They have a 45 day timeline (Appendix I, Table 7).

2.3 Category P Pre-submission Consultations (excluding joint reviews and subject to registration inquiries) have been added to the MOSP. They have an 80 day timeline but no fees (Appendix I, Table 8).

2.4 Category D URMULE pre-submissions and submissions will no longer be reported under the MOSP. Their management will be governed by the Memorandum of Understanding (MOU) between Agriculture and Agri-Food Canada and Health Canada. Performance targets are set in the MOU and are reported to the Joint Management Committee annually.

2.5 Performance reporting under the *User Fees Act* will apply to submissions subject to a fee under the revised cost recovery regulations that come into effect on 1 April 2017 or on the day the new Pest Control Product Fees and Charges Regulations come into force, whichever is later.

2.6 All data protection submissions will become Category L submissions.

3.0 Scope

This document pertains to all applications for:

- The registration or amendment of a pest control product,
- The specification of a maximum residue limit (MRL),
- The authorization or notification of research,
- The issuance of an equivalency certificate and authorisation of importation for own use,
- Pre-submission consultations,
- Extension of exclusive use protection, and
- Equivalency and data compensation assessments.

The same general process applies to all categories of submissions. However, some steps are not required for all categories. Depending on the purpose of the application and the type of information required, every submission subject to the MOSP is assigned to one of the eight following categories:

Category A

- New active ingredients or integrated system products, their related end-use products, and manufacturing-use products.
- Major new use of registered pest control products (defined as the addition of a new use-site category to the use pattern for a specific registered active ingredient).
- Specification of import MRLs for an unregistered active ingredient.

Category B

- New pest control products containing registered active ingredients.
- Amendment to existing pest control products (for example, product chemistry, labelling).
- Emergency registration.
- The addition of import MRLs for previously assessed active ingredients.

Category C

- Product registrations and amendments with no data requirements. These applications involve minor label or formulation reviews, such as product registration based on registered precedent products.

Category D

- Submissions within particular programs including:
    - Import for Manufacture and Export Program (IMEP),
    - Own Use Import (OUI),
    - Grower Requested Own Use (GROU) Equivalency and import permits,
    - Master Copies,
    - Private Labels,
    - Registration Renewal, and
    - Discontinuations.

Category E

- Research authorisations for new active ingredients and new use(s) of registered active ingredients.
- Research notification for research carried out in Canada.

Category F

- Registration and amendments to registered pest control products via notification.

Category L

- Submissions to register or amend products including new sources of technical grade active ingredient, manufacturing concentrates and end use products where the applicant wishes to use or rely upon data provided by another registrant.
- Requests to extend the exclusive use protection period based upon minor uses.

Category P

- Pre-submission consultations.

4.0 Instructions for Submitting an Application

Various guidance documents and instructions on submitting information are available on the Pesticides and Pest Management portion of Heath Canada's website to help applicants prepare a complete application package.

5.0 The Management of Submissions Policy Process

The following sections provide a step-by-step description of the submission review process.

Under the MOSP, applications are typically reviewed in chronological order within each MOSP category subdivision. However, under certain circumstances timelines may be adjusted:

- If there is a critical need, an expedited review[1] may be considered. The intent of expedited reviews is to meet the urgent needs of users of pest control products, to facilitate risk reduction or to address a public health or environmental concern. For example, a formulation amendment to replace a formulant of concern, or products needed to mitigate a public health or environmental risk may be expedited.
- Related submissions may be grouped in order to follow the same review timeline. The grouping of related submissions occurs when one submission depends upon the success of the other. For example, an end use product cannot be registered before the technical grade active ingredient is registered and conversely, an active ingredient must have a use associated with it to be registered.
- DIR2003-01 contains information on how the PMRA processes tailgater submissions which can result in atypical timelines for submissions. A tailgate submission is defined as a submission for a new or existing product for which a current submission is open, past screening and awaiting a regulatory decision. A tailgate submission cannot be reviewed until the previously submitted application has been accepted or proposed for registration. Tailgate submissions delay the processing of the original submission by causing the review to cease and refocus to encompass the amendment. The following options are given to the applicant of a tailgater submission: (a) withdraw the tailgate submission and resubmit when the precedent submission is approved; (b) maintain the tailgate submission but combine it with the precedent submission (adopt its category and status) and reset the timelines for the precedent submission to start at the time of the tailgate submission; or (c) screen and delay: that is, allow tailgate submission, perform preliminary screen and delay processing within the PMRA until the original submission is accepted for registration. During the delay status, any changes in scientific approach or new policies will apply to the submission in delay.
- PMRA sometimes receives submissions to expand, or change use patterns, or to make substantial amendments to the conditions of registration while a re-evaluation is underway. Thus, in order to reach consistent and timely regulatory decisions, PMRA coordinates the review of these pre-market submissions and the science review component of the re-evaluation. Consequently, PMRA applies any updated science findings to any subsequent (pre-market and post-market) decisions.

[1] Prior to considering an adjustment to a submission timeline for an expedited review the PMRA must have ascertained that the submission has a complete and reviewable data package.

The MOSP performance timelines in calendar days are summarized in Appendix I, Tables 1 to 8 (for Categories A to F, L and P respectively). Within each category there are further subdivisions (for example, submission subcategories, submission types, classes) that may have different performance timelines because they are conducted under specific programs (for example, Joint Review).

A submission flow diagram is depicted in Appendix II to illustrate the MOSP examination process for a standard Category A submission. Note: other categories will follow the same process using the performance timelines provided in Appendix I. However, some steps will not apply to every submission category and/or submission subdivision (for example, public consultation is not required for Category C submission decisions). Also, for some submission subdivisions the screening and review are combined, for example, master copy and private labels or in the case of notifications the completeness check and review are combined.

5.1 Completeness Check (Verification and Screening)

A completeness check will be performed on all submissions to ensure a complete submission has been received before the review stage is started. The performance timelines for the completeness check are outlined in Appendix I. When the submission is received by the PMRA, the completeness check clock will start. The completeness check will generally consist of an initial verification step and a more detailed screening step.

5.1.1 Verification

For most submission categories there is a seven-calendar-day verification step during which submissions are verified to ensure that non-data elements have been provided. Non-data elements may include the covering letter, the appropriate application form, the Statement of Product Specification Form, the Fee Form, the fee and the e-index. A submission found to be deficient at the verification step will result in an e-mail, outlining the deficiencies, being sent to the applicant and the submission being placed "on-hold". The applicant is given 14 calendar days to address the deficiencies. When a response is received from the applicant, a second verification period of a maximum of seven calendar days will apply and the completeness check clock will be reset to day 0. Lack of an adequate response will result in the submission being rejected.

Applicants are provided a submission number acknowledging receipt of the submission. This number should appear on all subsequent correspondence to the Agency relating to that submission.

5.1.2 Screening

For most submission categories there is a 30 calendar day screening step during which submissions are screened to ensure they meet the format, data and fee requirements of the PMRA before they are accepted for review.

Clarifications
The PMRA may request minor clarifications concerning submitted information by e-mail or facsimile (for example, clarification of the Statement of Product Specification Form). The applicant has 10 calendar days to respond to the clarification request; screening continues during this time. If an adequate response to the request for clarification is not provided within the timeframe specified, a Notice of Deficiencies will be issued. A Notice of Deficiencies can also be sent to the applicant when significant deficiencies are identified during screening.

Note: Clarifications may also be sent out during the review stage–refer to Section 5.2.

Notice of Deficiencies
During the screening stage, the PMRA will place a submission "on-hold" if deficiencies are identified in the application requirements, including fees, or if insufficient information has been submitted (for example, if required test data is missing). Note: deficiencies may also be identified during the review stage; refer to Section 5.2.

When a Notice of Deficiencies is issued at screening (at which time the completeness check clock stops), the applicant must respond to the Notice of Deficiencies within the timeframe specified in the notice, usually 45 calendar days, and provide all of the requested information as directed. (Note: When one submission in a group of related submissions is put "on-hold", all of the related submissions will also be put "on-hold"). When a response to the Notice of Deficiencies is received by the PMRA, the completeness check clock will be reset with 15 calendar days on the clock.

No reminders will be issued. If there is no response or if the response is incomplete or inadequate, the application will be denied in accordance with subsection 7(5) of the *Pest Control Products Act*, unless the applicant withdraws the application. Any submission that has been previously withdrawn by the applicant, or denied by the PMRA during a previous examination, may be re-submitted at a future date. It will be considered a new submission and assigned a new submission number.

5.2 Review Stage

The review stage includes the following activities:

- Science evaluation of the health and environmental risks and the value of the pest control product to determine if they are acceptable,
- the review of the bilingual product label, and
- the decision-making process.

The review times outlined in Appendix I are in calendar days allotted to the PMRA to conduct all of the steps in the review stage. Note: If related submissions have different review timelines, the longer review timeline will usually apply to all of the submissions in the group.

The review stage clock will start as soon as the completeness check is completed and appropriate fees have been paid. Invoices will be issued if a fee has not been received and the application will be placed on hold until the fee payment is received.

Excluded from the review time is the 45 calendar day public consultation period for major regulatory decisions (for example, new active ingredients and major new uses) conducted via the publication of a Proposed Registration Decision.

5.2.1 Science Evaluation

The PMRA may request clarifications of minor points on submitted data by e-mail or facsimile. The applicant has 10 calendar days to respond to the clarification request; the review continues during this time. If an adequate response to the request for clarification is not provided within the 10 calendar days, a Notice of Deficiencies will be issued, the submission will be placed "on-hold", and the review stage clock will stop. Note: As indicated previously, when one submission in a group of related submissions is placed "on-hold", all related submissions will also be put "on-hold".

If deficiencies are identified by a single science review stream at any time during the review stage, a Notice of Deficiencies will be sent to the applicant, the submission will be placed "on-hold", and the review stage clock will stop. The science review stream to which the deficiencies apply will stop that portion of the review; however, the remaining science review streams will continue to actively work on the submission during this time if this is possible, and determined to be efficient. The applicant is given a specified number of days (usually 90 calendar days) to fulfil the requirements outlined in the Notice of Deficiencies. There will be no reminders provided during the "on-hold" period. When the response is received within the required timeframe, the review stage clock will immediately restart and the affected science review stream will continue their review. Lack of a response within the required time frame will result in the application being denied in accordance with subsection 7(5) of the *Pest Control Products Act*, unless the applicant withdraws the submission.

The PMRA will issue one consolidated Notice of Deficiencies to the extent possible; however, in the event that deficiencies are identified by a second science review stream during the course of the first "on-hold", a second Notice of Deficiencies will be sent to the applicant and the review stage clock will remain stopped. The applicant will be given a specified number of days (usually 90 calendar days) from the time of the second Notice of Deficiencies to fulfil the identified data requirements. This new timeline will serve as the timeline for receipt of all data. Upon receipt of a response to a Notice of Deficiencies the science review stream for whom the deficiencies have been addressed will resume review of the submission; however, the review stage clock will remain "stopped" if any Notices of Deficiencies remain outstanding, and the review will remain on-hold for any science review stream for whom a Notice of Deficiencies remains outstanding.

The review stage clock will not restart until such time that a response to all outstanding Notices of Deficiencies has been received by the PMRA.

5.2.2 Label Review

To facilitate timely issuance of the approved product label, separate French and English labels must be submitted with the application. Provided the proposed product label is acceptable, the label review continues throughout the review process and the PMRA will make necessary label revisions to the proposed product label. Should extensive changes be required to the proposed product label the PMRA will request the applicant to make changes and provide an updated proposed product label during the review process. Where possible, translation of label revisions resulting from the science evaluation will be provided by the PMRA. The PMRA will communicate to the applicant any changes resulting from the science evaluation before finalizing the product label. This will provide an opportunity for the applicant to clarify issues arising from the label revisions.

5.2.3 Decision

If there is sufficient scientific evidence to show that a product does not pose unacceptable health or environmental risks and that it has value, a decision to issue an authorisation (i.e. permit) or register the product will be made. The applicant will receive a decision letter and at the same time, if applicable, the PMRA will issue the approved bilingual label and the certificate of registration.

5.3 Public Consultation

A bilingual consultation document (Proposed Registration Decision) is published for all major decisions (for example, new active ingredients and major new uses of registered pesticides) as defined under subsection 28(1) *Pest Control Products Act*.

The consultation period for a Proposed Registration Decision is 45 days from the date of publication. Any comments received during the consultation period are considered before a final decision is made, i.e. issuance of the final decision letter, approved label and certificate of registration.

5.4 Renegotiation of Review Timelines

Review times as detailed in Appendix I may need to be renegotiated by the PMRA and the applicant for the purpose of synchronizing the reviews of related submissions, or to allow for the review of additional information required to make a regulatory decision.

5.5 Measures

Completeness Check Time
The time taken from initial receipt of an application (or from when a response to a verification deficiency is received) to the end of the first screening.

Review Time
In general, the time after the completeness check is completed to when a final regulatory decision is made, excluding applicant time (when a submission is placed "on-hold" pending an applicant response to a Notice of Deficiencies) and excluding public consultation time.

Applicant Time
The time when a submission is pending an applicant to respond to a Notice of Deficiencies, in other words, when the completeness check or review clocks are "on-hold".

Total Time
From the date that an application is received to the date that the submission is registered, rejected, withdrawn, denied or completed.

Performance Standard
The PMRA's performance standard is that 90% of submissions in all categories are to be processed within the applicable review timelines.

***User Fees Act* Reporting**
For the purpose of reporting under the *User Fees Act*, the PMRA will calculate performance to reflect the average time to complete all submission types falling under each user fee review timeline within a submission category.

5.6 Dispute Resolution

To minimize disputes, applicants are encouraged to familiarize themselves with the pesticide registration process and registration requirements and to request, when appropriate, a pre-submission consultation.

The PMRA will make every effort to manage and resolve disputes at the organizational level at which they take place.

Disputes regarding the screening of an application, including: screening deficiencies, data requirements, and screening timeline should be addressed to the screening officer assigned to the submission.

Disputes regarding the review of the submission, including: review deficiencies, data requirements, review timeline, labelling revisions and review decision should be addressed to the administrative coordinator assigned to the submission.

If mechanisms for early dispute resolution fail, applicants should contact the Chief Registrar's Office of the PMRA. For major regulatory decision proposals, there is an opportunity for the applicant (or any member of the public) to comment during the public consultation period. In addition, for any major regulatory decisions for which a public consultation under section 28(1) of the *Pest Control Products Act* was required before a regulatory decision was taken, the applicant (or any member of the public) has another opportunity to comment by filing a Notice of Objection requesting the reconsideration of the decision within 60 days after the decision is made public.

For additional information on the reconsideration of decision process, please consult the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the Health Canada PMRA's Pest Management Information Service.

Appendix I MOSP Performance Timelines for Pest Control Product Applications

(MOSP Performance Standard = 90% of submissions to be processed within the applicable review timelines)

(User Fee Performance Target = average number of days for review)

Table 1 Category A Submission Performance Timelines in Number of Calendar Days (includes new active ingredients, new MRLs and major new use registration)

Category Subdivision	Completeness Check in Days	MOSP Review Time in Days (Months)[1]	Public Consultation in Days	User Fee Review Timeline in Days (Months)[1]
Conventional chemical	37	655 (22)	45	655 (22)
Import MRL[2]	37	655 (22)	n/a	
Reduced-risk[3], other biopesticides, non-conventionals, NSCLP[4]	37	555 (18.5)	45	555 (18.5)
Microbials including URMUR[6]	37	470 (15.5)	45	470 (15.5)
URMUR[6] for conventional chemical, Reduced-riskc, other biopesticides, non-conventionals, NSCLP[4]	37	470 (15.5)	45	
Pheromones – SCLP[5] including URMUR[6]	37	285 (9.5)	45	285 (9.5)
Joint reviews	Negotiated		45	Negotiated
Submissions with atypical timelines, for example, tailgater submissions, renegotiated timelines, synchronized timelines, coordination with re-evaluations	37 or variable	Variable	45	Variable

[1] Review time excludes the 45 day public consultation period if applicable and time when a submission is on hold pending the applicant
[2] Maximum Residue Limit
[3] Reduced-risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides.*
[4] Non Straight Chain Lepidopteran Pheromone
[5] Straight Chain Lepidopteran Pheromone
[6] User Requested Minor Use Registration

Table 2 Category B Submission Performance Timelines in Number of Calendar Days (includes new formulations, changes in current formulations, new hosts and/or pests added to existing products, new source of currently registered active ingredient, emergency registrations and changes in rates and methods of application)

Category Subdivision	Completeness Check in Days	MOSP Review Time in Days (months)[1]	User Fee Review Timeline in Days (Months)[1]
Conventional chemical including emergency use (priority)	37	425 (14)	425 (14)
New MRL for previously assessed active ingredient[2]	37	425 (14)	
Reduced-risk[3], other biopesticides, non-conventionals, NSCLP[4] including emergency use (priority)	37	360 (12)	360 (12)
Microbials including emergency use (priority)	37	240 (8)	240 (8)
Pheromones – SCLP[5] including emergency use (priority):	37	240 (8)	
Streamlined (application rate changes, tank mixes, new pests or changes to level of control)	37	158 (5)	158 (5)
Joint review	Negotiated	Negotiated	Negotiated
Submissions with atypical timelines, for example, tailgater submissions, renegotiated timelines, synchronized timelines, coordination with re-evaluations	37 or variable	Variable	Variable

[1] Review time excludes time when a submission is on hold pending the applicant
[2] Maximum Residue Limit
[3] Reduced-risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides.*
[4] Non Straight Chain Lepidopteran Pheromone
[5] Straight Chain Lepidopteran Pheromone

Table 3 Category C Submission Performance Timelines in Number of Calendar Days (includes changes to technical grade active ingredient, product chemistry, new or changed labels, similar products, administrative changes or re-instatements)

Category Subdivision[2]	Completeness Check Time in Days	MOSP Review Time in days (months)[1]	User Fee Review Timeline in Days (Months)[1]
New/Changes TGAI or ISP Product Chemistry (C.1)	37	180 (6)	180 (6)
New/Changes to EP or MA Product Chemistry (C.2)			
Administrative Changes (C.6.2)			
Administrative Re-instatement (C.9)			
New/Changes to Product Labels (C.3)	37	240 (8)	240 (8)
Addition of approved minor use (C.6.3)[3]			
Similar Product (C.7)			
Upgrade to Initial or Master Product (C.8)[4]	See category F	See category F	See category F
Submissions with atypical timelines, for example, tailgater submissions, renegotiated timelines, synchronized timelines, coordination with re-evaluations	37 or variable	Variable	Variable

[1] Review time excludes time when a submission is on hold pending the applicant.

[2] Category C submission types are: new products based on precedent (C.7), label amendments (C.3) and formulation amendments (C.2). Should a Category C application be received with multiple submission types the longer timeline will be applied. For example, if an application includes both formulation amendments (C.2) and label amendments (C.3), the review timeline will be 8 months.

[3] Addition of approved minor use (C.6.3): Adding a Minor Use approved under the URMULE program to full product label would fall under the longer timeline.

[4] Upgrade to Initial or Master Product Category C applications are usually combined with other Category C submission types and will therefore be subject to the timeline of the associated Category C submission type. Upgrades to initial or master product status with no additional changes to the registration may be made under the Notification/Non-notification Policy.

Table 4 Category D Submission Performance Timelines in Number of Calendar Days

Category Subdivision	Completeness Check Time in Days	MOSP Review Time in Days[1]	User Fee Review Timeline in Days[1]
IMEP	21	46	46
OUI equivalency certificate	21	70	n/a
OUI permit	30 days total time		n/a
GROU equivalency certificate	To be determined	To be determined	n/a
GROU permit	30 days total time		n/a
Master copy	7 verification	42 screen and review	42 screen and review
Private label	7 verification	10 screen and review	10 screen and review
Registration renewal	Complete by March 15th		Number of days from the issuance of the renewal notice to March 15 of the following year
Discontinuation	7 verification	45 screen and review	n/a
Submissions with atypical timelines, for example, tailgater submissions, renegotiated timelines, synchronized timelines, coordination with re-evaluations	37 or variable	Variable	Variable

[1] Review time excludes time when a submission is on hold pending the applicant.

Table 5 Category E Submission Performance Timelines in Number of Calendar Days (for research authorisations and research notification)

Category Subdivision	Completeness Check Time in Days	MOSP Review Time in Days[1]	User Fee Review Timeline in Days[1]
New technical grade active ingredient (food and non-food use)	21	159	159
New use	21	69	69
Notification of research	30 days total		30 days total

[1] Review time excludes time when a submission is on hold pending the applicant.

Table 6 Category F Submission Performance Timelines in Number of Calendar Days (Notifications)

Category Subdivision	MOSP Review Time in Days[1]	User Fee Review Timeline in Days[1]
All Notifications	45 days total time	45 days total time

[1] Review time excludes time when a submission is on hold pending the applicant.

Table 7 Category L Submission Performance Timelines in Number of Calendar Days (Data protection submissions)

Category Subdivision		Completeness Check Time in Days	MOSP Review Time in Days[1]	User Fee Review Timeline in Days[1]
Equivalency and data compensation assessment TGAI, EP and MA with no data		365 day total time		365 days total time
Equivalency and data compensation assessment EP and MA with partial data package	Conventional Chemical	37	425	425
	Reduced-risk[2], other biopesticides, non-conventionals, NSCLP[3]	37	360	360
	Microbial and SCLP[4]	37	240	240
Regulatory Decision		45 days total time		n/a
Requests to extend the exclusive use protection period based upon minor uses		37	240	n/a
Submissions with atypical timelines, for example, tailgater submissions, renegotiated timelines, synchronized timelines, coordination with re-evaluations		37 or varies	Varies	Varies

[1] Review time excludes time when a submission is on hold pending the applicant.
[2] Reduced-risk refers to the expedited review timelines as outlined in Regulatory Directive DIR2002-02, *The PMRA Initiative for Reduced-Risk Pesticides.*
[3] Non Straight Chain Lepidopteran Pheromone
[4] Straight Chain Lepidopteran Pheromone

Table 8 Category P Submission Performance Timelines in Number of Calendar Days (Pre-submission Consultations)

Category Subdivision	Completeness Check Time in Days	MOSP Review Time in Days[1]	User Fee Review Timeline in Days[1]
Pre-submission Consultation[2]	80 days total time		n/a

[1] Review time excludes time when a submission is on hold pending the applicant.
[2] Excludes joint review pre-submission consultations and subject to registration inquiries.

Appendix II Submission Process Using Category A as an Example